

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

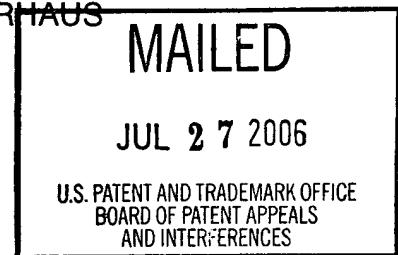
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JAN C. SIMON, CHRISTOPH M. SCHEMPP,
ERWIN SCHOEPF, and BIRGIT SIMON-HAARHAUS

Appeal No. 2006-0208
Application No. 09/856,694

ON BRIEF



Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

REMAND TO THE EXAMINER

This case is being remanded to the examiner for clarification of the rejections made under 35 U.S.C. § 103(a).

Claim 36 is representative of the subject matter on appeal, and reads as follows:

36. A method for treating a condition, comprising administering to a subject in need thereof an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) active agent consisting of (i) hyperforin or (ii) hyperforin and hypericin, wherein said condition is selected from the group consisting of an inflammatory skin condition, a precancerous condition, a geriatric skin condition, and a microbial skin infection.

DISCUSSION

Claims 36-45 and 56 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of the Hypericum Homepage,¹ Merck,² Shroot³ and Lacefield.⁴ In addition, claims 36, 38-45 and 56 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Valavicius⁵ and Chavez,⁶ or the combination of Valavicius, Chavez, Hypericum Homepage and Decosterd.⁷

In the rejection of claims 36-45 and 56 under 35 U.S.C. § 103(a) as being obvious over the combination of Hypericum Homepage, Merck, Shroot and Lacefield, the Hypericum Homepage reference is cited for teaching that extracts of St. John's Wort, when applied topically, exhibit anti-inflammatory and antibacterial effects, and that those effects are attributed to the presence of hyperforin in the extract. See Examiner's Answer, page 4. From the teachings of the Hypericum Homepage, the examiner concludes that "since hyperforin was a known and commercially available product at the time of the claimed invention

¹ Bloomfield et al., (Hypericum Homepage), Hypericum & Depression, Ed. J. Sedillos, Prelude Press (1996), copy made available from hypericum.com; <http://hypericum.com/hyp20.htm>.

² The Merck Manual, Copyright 1995-2002,
<http://www.merck.com/pubs/mmanual/section10/chapter111/111a.htm>

³ Shroot et al. (Shroot), U.S. Pat. No. 5,151,534, issued September 29, 1992.

⁴ Lacefield et al. (Lacefield), U.S. Pat. No. 4,021,553, issued May 3, 1977.

⁵ Valavicius et al. (Valavicius), "Antitumor Activity of Herbs of the Lithuanian SSR," Trudy Akademii Nauk Litovski, SSR, Series B, pp. 110-113 (a986), translation by Ralph McElroy Translation Company.

⁶ Chavez et al. (Chavez), "Saint John's Wort," Hospital Pharmacy, Vol. 32, No. 12, pp. 1621-1632 (1997).

⁷ Decosterd et al. (Decosterd), "New Hyperforin Derivatives from Hypericum revolutum VAHL with Growth-Inhibitory Activity against a Human Colon Carcinoma Cell Line," Helvetica Chimica Acta, Vol. 77, pp. 464-471 (1989).

(see specification, page 12), it would have been obvious to one of ordinary skill in the art to use hyperforin . . . in a method for treating inflammatory skin conditions because of its disclosed anti-inflammatory effect.” Id.

In response, appellants argue that the statement in the Hypericum Homepage relied upon in the rejection cites to a reference, which may be a better reference; but that reference was not cited and the contents are not known, and that “[i]n fact, this reference may not support the PTO’s case at all.” Reply Brief, page 2.

The Hypericum Home Page simply states that “[a]nti-inflammatory and antibacterial effects of externally applied St. John’s Wort preparations have been reported and attributed to the presence of hyperforin,” id. at 101, and cites to reference (1).⁸ We agree with appellants that reference (1) should be made of record, as the statement in the Hypericum Home Page merely appears to be based on more explicit and/or comprehensive evidence, which may or not support the examiner’s interpretation.

In regard to the rejection of claims 36, 38-45 and 56 under 35 U.S.C. § 103(a) as being anticipated by the combination of Valavicius and Chavez, the examiner contends that since Valavicius teaches that St. John’s Wort extracts inhibit the growth of sarcoma cells and tumors in various organs in rats, it would have obvious to use hyperforin since at the time of the invention it was known in

⁸ Reference (1) appears to be to “ESCAP Proposal for the Summary of Product Characteristics,” 3rd Version May 1994. HHP at 116.

the art that St. John's Wort contains high concentrations of hyperforin. See Examiner's Answer, page 7.

Valavicius, however, states that St. Johns Wort is known to have multiple active ingredients, such as novoimanin, which is topically used in cases of infectious wounds, burns, trophic ulcers and gynecological diseases; and catechols, which have vitamin P activity. See Translation at page 1. Thus, there is nothing in the reference that would suggest that hyperforin was the active agent, and Chavez does not appear to make up that deficiency as that reference was merely relied upon for teaching that St. John's Wort contains high concentrations of hyperforin. See Examiner's Answer, page 7.

Claims 36, 38-45 and 56 also stand rejected under 35 U.S.C. § 103(a) as being anticipated by the combination of Valavicius, Chavez, Hypericum Homepage and Decosterd.

The Hypericum Homepage is relied upon for teaching that hypercin has "been proven to possess promising anticancer properties and has been shown to inhibit growth of gliomas (brain tumors) (103), lung cancer (104) and skin cancer (68) in vitro (in the laboratory)." There is no mention, however, of hyperforin, and claim 38 requires the use of hyperforin or a mixture of hyperforin and hypercin. Decosterd does not make up for that deficiency as that reference relates to the growth-inhibiting activity of two compounds isolated from Hypericum revelutum, a shrub native to South-East Africa. Decosterd's only reference to the biological activity of hyperforin is as an antibiotic.

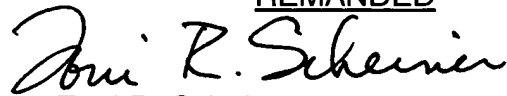
Thus, upon return of the application, the examiner may wish to reconsider the rejections of claims 36, 38-45 and 56 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Valavicius and Chavez, or the combination of Valavicius, Chavez, Hypericum Homepage and Decosterd.

FUTURE PROCEEDINGS


This remand to the examiner pursuant to 37 CFR § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. Accordingly, 37 CFR § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this remand by the Board.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (8th ed., rev. 3, August 2005). It is important that the Board be informed promptly of any action affecting the appeal in this case.

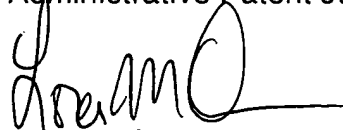
REMANDED

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Toni R. Scheiner)
Administrative Patent Judge)

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Donald E. Adams)
Administrative Patent Judge)

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Lora M. Green)
Administrative Patent Judge)

) BOARD OF PATENT

) APPEALS AND

) INTERFERENCES

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